

(d) The petition must contain a certification that the petitioner has served a true and complete copy of the petition on interested parties by certified or registered mail (return receipt requested) or by personal delivery.

§ 124.31 Applicant response to petition.

(a) The applicant may file with APHIS a written response to the petition no later than 20 days after the applicant's receipt of a copy of the petition.

(b) The applicant's response may present additional facts and circumstances to address the assertions in the petition, but shall be limited to the issue of whether the applicant acted with due diligence during the regulatory review period. The applicant's response may include documents that were not in the original patent term extension application.

(c) If the applicant does not respond to the petition, APHIS will decide the matter on the basis of the information submitted in the patent term restoration application, the due diligence petition, and APHIS records.

§ 124.32 APHIS action on petition.

(a) Within 90 days after APHIS receives a petition filed under § 124.30, the Under Secretary for Marketing and Regulatory Programs shall make a determination under paragraphs (b) or (c) of this section or under § 124.33 whether the applicant acted with due diligence during the regulatory review period. APHIS will publish its determination in the FEDERAL REGISTER together with factual and legal basis for the determination, notify PTO of the determination in writing, and send copies of the determination to PTO, the applicant, and the petitioner.

(b) APHIS may deny a due diligence petition without considering the merits of the petition if:

(1) The petition is not filed in accordance with § 124.30;

(2) The petition does not contain information or allegations upon which APHIS may reasonably determine that the applicant did not act with due diligence during the applicable regulatory review period; or

(3) The petition fails to allege a sufficient total amount of time during

which the applicant did not exercise due diligence so that, even if the petition were granted, the petition would not affect the maximum patent term extension which the applicant is entitled to under 35 U.S.C. 156.

[59 FR 11369, Feb. 25, 1993, as amended at 64 FR 43045, Aug. 9, 1999]

§ 124.33 Standard of due diligence.

(a) In determining the due diligence of an applicant, APHIS will examine the facts and circumstances of the applicant's actions during the regulatory review period to determine whether the applicant exhibited the degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. APHIS will take into consideration all relevant factors, such as the amount of time between the approval of an experimental use permit and licensure of the veterinary biological product.

(b) For purposes of this Part, the actions of the marketing applicant shall be imputed to the applicant for patent term restoration. The actions of an agent, attorney, contractor, employee, licensee, or predecessor in interest of the marketing applicant shall be imputed to the applicant for patent term restoration.

Subpart E—Due Diligence Hearing

§ 124.40 Request for hearing.

(a) Any interested person may request, within 60 days beginning on the date of publication of a due diligence determination by APHIS in accordance with § 124.32, that APHIS conduct an informal hearing on the due diligence determination.

(b) The request for a hearing must:

(1) Be in writing;

(2) Contain the docket number of the FEDERAL REGISTER notice of APHIS's regulatory review period determination;

(3) Be delivered to the Director, Center for Veterinary Biologics, Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, IA 50010—8197.